II. REMARKS

Preliminary Remarks

Claims 1 and 4-20 are amended, and new claim 25 is added. Upon entry of the amendment, claims 1 and 4-25 will be pending.

Step (a) of claim 1 is amended to specify:

"programming the start of a treatment cycle comprising COS by inducing the start of menses by administering a compound selected from the group consisting of a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation, and a combination thereof,

wherein the LHRH antagonist is selected from the group consisting of cetrorelix, teverelix, ganirelix, antide, and abarelix and is administered at a dosage range between 0.5 mg to 10 mg during the luteal phase of the menstrual cycle preceding the treatment cycle, and

wherein the progestogen only preparations and/or the combined oral contraception preparations are administered starting during the luteal phase of the menstrual cycle prior to the preceding menstrual cycle, or on day 1 or 2 of the preceding menstrual cycle."

Support for the amendment of step (a) of claim 1 is found in the specification, for example, on page 3, line 24, to page 4, line 7.

Step (b)-(e) of claim 1 are amended for grammatical consistency and enhanced clarity.

Step (e) of claim 1 is further amended by deleting the phrase beginning with the word "especially," the subject matter of which is present in new claim 25.

Claim 4 is amended for grammatical consistency and enhanced clarity.

Claims 5-9 are amended to identify the LHRH antagonist to which the claims refer as that which is administered in step (c) as described, for example, on page 4, lines 5-8.

Claims 10-20 are amended to specify administration according to step (a) of claim 1 as described, for example, on page 3, lines 24-34.

New claim 25 specifies disclosed assisted reproductive techniques as described, for example, on page 2, lines 13-16.

Patentability Remarks

35 U.S.C. §112, first paragraph, written description

A. Claims 1 and 4-24 are rejected under 35 U.S.C. §112, first paragraph, for lack of written description, because the application allegedly does not provide descriptive support for the reference to "resetting the menstrual cycle," in claim 1 as amended by the response to the previous official action.

The applicants submit that the specification clearly describes a method of programming controlled ovarian stimulation procedures that comprises administering a preparation that induces the start of menses on a desired date (*e.g.*, *see* page 3, lines 24-34). One of skill in the art at the time the priority application was filed would clearly understand the reference in claim 1 to "resetting the menstrual cycle" to refer to the disclosed step of administering a preparation to induces the start of menses on a desired date. Nonetheless, in order to expedite prosecution, step (a) of claim 1 is amended by replacing the expression "resetting the menstrual cycle," with the phrase "programming the start of a treatment cycle comprising COS by inducing the start of menses," as described in the application.

B. Claims 1 and 4-24 are further rejected under 35 U.S.C. §112, first paragraph, for lack of written description, because the application is not considered to provide descriptive support for a method wherein a progestogen only preparation and/or a combined oral contraceptive preparation is administered "starting during both the luteal phase and day 1 or 2 of the menstrual cycle."

Step (a) of claim 1 is amended to specify administering a compound selected from the group consisting of a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation, and a combination thereof, wherein the LHRH antagonist is selected from the group consisting of cetrorelix, teverelix, ganirelix, antide, and abarelix and is administered at a dosage range between 0.5 mg to 10 mg during the luteal phase of the menstrual cycle preceding the treatment cycle, and wherein the progestogen only preparations and/or the

combined oral contraception preparations are administered starting during the luteal phase of the menstrual cycle prior to the preceding menstrual cycle, or on day 1 or 2 of the preceding menstrual cycle. Descriptive support for the amendment of step (a) of claim 1 is found in the application, *e.g.*, on page 3, line 24, to page 4, line 7.

Withdrawal of the rejection of claims 1 and 4-24 under 35 U.S.C. §112, first paragraph, for lack of written description is respectfully requested.

35 U.S.C. §112, second paragraph

A. Claims 1 and 4-24 are rejected under 35 U.S.C. §112, second paragraph, because the precise meaning of the reference in claim 1 to administering a progestogen only preparation and/or a combined oral contraceptive preparation "starting during both the luteal phase and day 1 or 2 of the menstrual cycle" is considered to be unclear.

As discussed above, step (a) of claim 1 is amended to specify administering a compound selected from the group consisting of a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation, and a combination thereof, wherein the LHRH antagonist is selected from the group consisting of cetrorelix, teverelix, ganirelix, antide, and abarelix and is administered at a dosage range between 0.5 mg to 10 mg during the luteal phase of the menstrual cycle preceding the treatment cycle, and wherein the progestogen only preparations and/or the combined oral contraception preparations are administered starting during the luteal phase of the menstrual cycle prior to the preceding menstrual cycle, or on day 1 or 2 of the preceding menstrual cycle. The precise meaning of claim 1 as amended would be clear to one of skill in the art.

B. Claims 1 and 4-24 are further rejected under 35 U.S.C. §112, second paragraph, because the phrase in step (e) of claim 1 beginning with the word "especially" is considered to make the claim indefinite.

As discussed above, step (e) of claim 1 is amended by deleting the expression, "especially IVF, ICSI, GIFT, ZIFT or intrauterine insemination via sperm injection," and the

subject matter of the deleted expression is submitted in new claim 25. The meaning and metes and bounds of claim 1 as amended are therefore clear to one of skill in the art.

C. Claims 1 and 4-24 are also rejected under 35 U.S.C. §112, second paragraph, because the meaning of the term "the LHRH antagonist" in claims 5-9 is considered to be indefinite.

Claims 5-9 are amended to identify the LHRH antagonist to which the claims refer as that which is administered in step (c) of claim 1.

Withdrawal of the rejections of claims 1 and 4-24 under 35 U.S.C. §112, second paragraph, is respectfully requested.

35 U.S.C. §103(a)

A. Claims 1, 4, 5, 7, 10, 11, 16, 18, and 21-24 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of Felberbaum et al. (1997) or Albano et al. (1996) or Engel et al. (1997) or Olivennes et al. (1994), considered in combination with Ziegler et al. (1998), and further in combination with Garfield et al. (U.S. Patent No. 5,470,847) or Hall et al. (1991).

The four alternative primary references (Felberbaum et al., Albano et al., Engel et al., and Olivennes et al.) describe protocols of controlled ovarian stimulation (COS) in which HMG is administered starting on day 2 of the treatment cycle for ovarian stimulation, and an LHRH antagonist is administered starting on day 4 or 5 of the cycle to prevent premature ovulation, HCG is administered when a sufficient number of follicles of sufficient diameter was observed, and oocytes are recovered and used in the application of assisted reproductive techniques (ART).

None of the cited primary references describe or suggest a method for therapeutic management of infertility and increasing the quality of fertilized oocytes and embryos by programming COS and ART that comprise programming the start of a treatment cycle comprising COS by inducing the start of menses by administering a compound selected from the group consisting of a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation, and a combination thereof, wherein the LHRH antagonist is administered during the luteal phase of the menstrual cycle preceding the treatment cycle, and wherein the progestogen only preparations and/or the combined oral contraception preparations

are administered starting during the luteal phase of the menstrual cycle prior to the preceding menstrual cycle, or on day 1 or 2 of the preceding menstrual cycle, as specified in claim 1.

The examiner cites Ziegler et al. as teaching the desirability of timing the onset of controlled ovarian hyperstimulation (COH), and alleges that at the time the invention was made it would have been obvious for one of ordinary skill in the art to modify a method for COS and ART as described by Felberbaum et al., Albano et al., Engel et al., or Olivennes et al., "by providing advanced timing via administration of a composition to allow for improved scheduling of treatments," with "the expectation of improving the efficiency of treatment scheduling and thus fertilization success with the advanced timing method." *See* pages 10-11 of the official action.

The examiner describes Garfield et al. as teaching that a progesterone-only or a combined estrogen-progesterone preparation can be administered as an oral contraceptive that inhibits the synthesis of LHRH and prevents the LH surge required for ovulation (for example, *see* col. 2, lines 17-47). *See* page 11 of the official action.

The examiner cites Hall et al. for its teaching that administering three daily doses of a LHRH antagonist during the mid-luteal phase caused "dramatic" decreases in blood concentrations of estrogen and progestogen, and induced luteolysis and the onset of menstrual bleeding within 24-48 hours after the final day of LHRH antagonist administration in all subjects. *See* page 997, bottom of left column. The examiner observes that the LHRH antagonist was administered with a dosage of 150 μg/kg, and alleges that it would have been obvious to vary or optimize the amount of LHRH antagonist administered during the luteal phase as the determination of optimum or workable ranges is routine experimentation. The examiner observes that Hall et al. disclose administering the LHRH antagonists specified in claim 1 (cetrorelix, teverelix, ganirelix, antide, or abarelix), but alleges that it would have been obvious to do so, since these are disclosed in the primary references. *See* pages 11-13 of the official action.

The examiner alleges that it would have been obvious to combine the methods of the primary references with that of Ziegler et al., to obtain a method of programming the timing of COS/ART in which an estrogen-only preparation is administered during the cycle preceding

COS/ART that comprises administering an LHRH antagonist during the follicular phase, and then to further modify said method to administer (i) a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation, or (ii) an LHRH antagonist during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures, in view of the teachings of Garfield et al. regarding oral contraceptive preparations, or the teachings of Hall et al. regarding LHRH antagonists. *See* page 13 of the official action.

To establish a *prima facie* case of obviousness, the examiner must show that the prior art references themselves or the knowledge generally available to one of ordinary skill in the art would (1) provide some suggestion or motivation to modify or combine reference teachings to obtain the claimed invention, (2) teach or suggest all of the claim limitations, and (3) provide a reasonable expectation that the claimed invention can be made or used successfully. *In re* Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See* M.P.E.P. § 2142.

In determining if there is obviousness in the first instance, "it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re* Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See* M.P.E.P. § 2142.

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. *In re* Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Obviousness does not require absolute predictability, however, at least some degree of predictability is required. *In re* Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be

found in the prior art, and not based on applicant's disclosure." *In re* Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Combining prior art references without evidence of a suggestion, teaching, or motivation "simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." *See* Ecolochem, Inc. v. Southern California Edison Co., 227 F.3d 1361, 1371-72; 56 U.S.P.Q.2d 1065 (C.A.Fed. - Cal., 2000).

As discussed above, the four primary references, Felberbaum et al., Albano et al., Engel et al., and Olivennes et al., describe protocols for COS and ART comprising administering HMG starting on day 2 of the treatment cycle for ovarian stimulation, administering an LHRH antagonist during the follicular phase of the cycle to prevent premature ovulation, administering HCG to induce ovulation, recovering oocytes and applying ART. None of the primary references describe or suggest performing such a method of COS and ART comprising programming the start of the treatment cycle by inducing the start of menses by administering a compound selected from the group consisting of a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation, and a combination thereof, wherein the LHRH antagonist is administered during the luteal phase of the menstrual cycle preceding the treatment cycle, and wherein the progestogen only preparations and/or the combined oral contraception preparations are administered starting during the luteal phase of the menstrual cycle prior to the preceding menstrual cycle, or on day 1 or 2 of the preceding menstrual cycle, as specified in claim 1.

Ziegler et al. describe a method for "timing assisted reproductive techniques (intrauterine insemination and in-vitro fertilization) in the natural cycle" that comprises administering estradiol starting about 7 days before the onset of menses and continuing for about 5 days, until the first Tuesday following the onset of menses, defined as functional day (FD) 0; starting daily administration of HMG on FD3 (Friday) that is continued for about 11 days, on average, of HMG treatment; and then administering HCG to induce ovulation. The method of Ziegler et al. delays the intercycle elevation of FSH but does not affect the timing of the onset of menstrual bleeding, which is described as being regulated by progesterone (*see* page 562, right column). Ziegler et al. expressly describe their method as one that permits an advanced timing of the onset

of controlled ovarian hyperstimulation (COH) treatments "when gonadotrophin-releasing hormone (GnRH) agonists are not used," and as having practical applications for timing ART "in the natural cycle." *See* page 561, left column.

In contrast to the method described by Ziegler et al., in which an estrogen-only preparation that does not affect menses is administered during the cycle preceding COS/ART, the claimed invention comprises administering (i) a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation, or (ii) an LHRH antagonist during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures that include administering an LHRH antagonist during the follicular phase to suppress premature ovulation.

The examiner alleges that it would have been obvious to combine the methods of the primary references with that of Ziegler et al., in view of Garfield et al. to obtain a method of programming the timing of COS/ART in which a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation is administered during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures. In contrast to the examiner's allegation, Ziegler et al. expressly teach away from performing such a method. Ziegler et al. specifically caution against practicing methods for programming the onset of a COH protocol that comprise administering an oral contraceptive during the preceding cycle, because the synthetic molecules present in oral contraceptives "may have persistent and deleterious effects notably on the endometrium and ovarian response to HMG." *See* page 563, left column. One of ordinary skill in the art at the time the invention was made therefore would not have been motivated to combine the methods of the primary references with that of Ziegler et al., in view of Garfield et al. to obtain a method of programming the timing of COS/ART in which a progesterone-containing oral contraceptive preparation is administered during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures. Furthermore, while one of ordinary skill in the art at the time the invention was made would not have been able to predict the results that would be obtained by such a method, he or she would reasonably have expected that such a method would be unsuccessful due to persistent and deleterious effects on the endometrium and ovarian response to HMG, as taught by Ziegler et al. as discussed above.

The examiner also alleges that it would have been obvious to combine the methods of the primary references with that of Ziegler et al., in view of Hall et al. to obtain a method of programming the timing of COS/ART in which an LHRH antagonist is administered during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures, "with the expectation of providing control of menstrual phases to provide advanced timing" for ART (*see* page 13 of the official action). Contrary to the examiner's allegation, at the time the invention was made, one of ordinary skill in the art would not have performed the claimed method with a reasonable expectation of success. At the time the invention was made, LHRH antagonists were considered by persons of ordinary skill in the art to interfere with mechanisms involved in germinal vesicle breakdown and the cell signaling pathway driving the oocyte into metaphase II (*see* De la Fuente et al, 1999, Human Reproduction, 14: 3060-3068, copy attached), and to be capable of compromising the mitotic program of cells undergoing folliculogenesis, blastomere formation and endometrium development (*see* Hernandez, 2000, Human Reproduction 15(6):1211-1216, abstract attached). Moreover, at the time the invention was made, it was known that FSH preserves early antral follicles from atresia during the luteal-follicular transition, and ensures their subsequent growth (*e.g.*, *see* Chun et al., 1996, Endocrinology 137:1447-1456, abstract attached), and that administration of an LHRH antagonist during the luteal phase results in significant decreases in blood concentrations of FSH, LH, estrogen, and progestogen, and prompt luteolysis (*see* Hall et al., page 997), which would reasonably be expected to deprive the follicles of the beneficial effects of FSH. In addition, Hall et al. teach that the cycle following induction of luteolysis by an LHRH antagonist was lengthened by about 6 days, and that further study is needed to determine if this difference is the result of altered gonadotropin dynamics after administration of the antagonist and possible effects of these on the developing follicle" (*see* page 999, middle of left column). Accordingly, at the time the invention was made, one of ordinary skill in the art would have expected that administration of an amount of LHRH antagonist during the luteal phase sufficient to induce luteolysis and the start of menses would interfere with oocyte meiosis and the mitotic programs of cells undergoing folliculogenesis, blastomere formation and endometrium development, and would promote atresia of developing follicles. One of ordinary skill in the art at the time the invention was made therefore would not reasonably have expected that administration of an

amount of an LHRH antagonist during the luteal phase sufficient to induce luteolysis and the start of menses would effectively program the scheduling of a successful COS/ART procedure, as alleged by the examiner. Prior to the successful demonstration of the efficacy of the claimed invention, it was not known if the timing of successful COS/ART procedures could be effectively programmed by administering a dosage of an LHRH antagonist during the luteal phase of the preceding cycle that induces the start of menses. Surprisingly, rather than having a deleterious effect upon the developing oocyte and supportive tissues, the claimed method provides for successful programming of COS/ART procedures with the advantage that follicular development is coordinated so that an increased number of high quality, mature follicles of similar size is produced for ART, as described in the Declaration of Dr. Riethmüller-Winzen that was submitted with the previous response.

In view of the foregoing, withdrawal of the rejection of claims 1, 4, 5, 7, 10, 11, 16, 18, and 21-24 under 35 U.S.C. §103(a) as having been obvious in view of Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al., in combination with Ziegler et al. (1998), and further in combination with Garfield et al. or Hall et al., is respectfully requested.

B. Claims 6, 8, 9, 17, 19, and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of (i) Felberbaum et al. (1997) or Albano et al. (1996) or Engel et al. (1997) or Olivennes et al. (1994), considered in combination with (ii) Ziegler et al. (1998), and further in combination with (iii) Garfield et al. or Hall et al. (1991), as applied to claims 1, 4, 5, 7, 10, 11, 16, 18, and 21-24, and further in view of Deghengi (U.S. Patent No. 5,945,128) or Rabasseda (1999).

The teachings of Felberbaum et al., Albano et al., Engel et al., Olivennes et al., Ziegler et al., Garfield et al., and Hall et al., as applied by the examiner to claims 1, 4, 5, 7, 10, 11, 16, 18, and 21-24, are discussed above.

Deghengi is described by the examiner as teaching that cetrorelix, teverelix, ganirelix, and antide were known to be the LHRH antagonists.

Rabasseda is described by the examiner as teaching that LHRH antagonists such as cetrorelix, ganirelix, and abarelix were known to be useful for treating female infertility.

As discussed above, one of ordinary skill in the art at the time the invention was made would not have been motivated to combine the methods of the primary references with that of Ziegler et al., in view of Garfield et al. or Hall et al., to obtain a method of programming the timing of COS/ART in which (i) a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation, or (ii) an LHRH antagonist, is administered during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures, with a reasonable expectation of success. The teachings of Deghengi and Rabasseda regarding the disclosed LHRH antagonists do not remedy the deficiencies of the cited references discussed above to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a). Accordingly, withdrawal of the rejection of claims 6, 8, 9, 17, 19, and 20 under 35 U.S.C. §103(a) as having been obvious in view of Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al., in combination with Ziegler et al. taken with Garfield et al. or Hall et al., and further in view of Deghengi or Rabasseda, is respectfully requested.

C. Claims 12-15 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of (i) Felberbaum et al. (1997) or Albano et al. (1996) or Engel et al. (1997) or Olivennes et al. (1994), considered in combination with (ii) Ziegler et al. (1998), and further in combination with (iii) Garfield et al. or Hall et al. (1991), as applied to claims 1, 4, 5, 7, 10, 11, 16, 18, and 21-24, and further in view of Kent (U.S. Patent No. 4,016,259).

The teachings of Felberbaum et al., Albano et al., Engel et al., Olivennes et al., Ziegler et al., Garfield et al., and Hall et al., as applied by the examiner to claims 1, 4, 5, 7, 10, 11, 16, 18, and 21-24, are discussed above.

Kent is described by the examiner as disclosing that the combination of progesterone and estrogen such as mestralon and ethinylestradiol is useful in animal contraception.

As discussed above, one of ordinary skill in the art at the time the invention was made would not have been motivated to combine the methods of the primary references with that of Ziegler et al., in view of Garfield et al. or Hall et al., to obtain a method of programming the timing of COS/ART in which (i) a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation, or (ii) an LHRH antagonist, is administered during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures, with a

reasonable expectation of success. The disclosure of Kent regarding an estrogen-progesterone combination for oral contraception does not remedy the deficiencies of the cited references discussed above to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a). Accordingly, withdrawal of the rejection of claims 12-15 under 35 U.S.C. §103(a) as having been obvious in view of Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al., in combination with Ziegler et al. taken with Garfield et al. or Hall et al., and further in view of Kent, is respectfully requested.

Judicially Created Doctrine of Obviousness Double Patenting

Claims 1 and 4-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 of Engel et al., in view of Ziegler et al., Hall et al., Deghengi, Rabasseda, and Kent, as applied above.

The applicants submit that at the time the invention was filed, one of ordinary skill in the art would not have been motivated to combine the method of claims 1-6 of U.S. Patent No. 6,319,192 with that of Ziegler et al., in view of Garfield et al., Hall et al., Deghengi, Rabasseda, and Kent, to obtain a method of programming the timing of COS/ART in which (i) a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation, or (ii) an LHRH antagonist, is administered during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures, with a reasonable expectation of success. One of ordinary skill in the art at the time the invention was filed could not reasonably have predicted the effects of administering a progesterone-only or a combined estrogen-progesterone oral contraceptive preparation, or an LHRH antagonist, during the preceding cycle to induce the timed onset of menstrual bleeding prior to the start of COS/ART procedures, and would reasonably have expected such a step to cause deleterious effects that would prevent successful operation of the COS/ART procedures, as discussed above. Accordingly, withdrawal of the rejection of claims 1 and 4-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 of Engel et al., in view of Ziegler et al., Hall et al., Deghengi, Rabasseda, and Kent, as applied above, is respectfully requested.

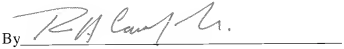
III. CONCLUSION

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If the examiner identifies any points that he feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Please charge any fees or credit any overpayments associated with the submission of this response to Deposit Account Number 03-3975.

Respectfully submitted,

Date: August 24, 2006

By 

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